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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,527	10/25/2001	Henri Hansson	23544-7004	3275

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,527

Applicant(s)

HANSSON ET AL.

Examiner

Francisco C. Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-18-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed October 18, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 17-33 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "and on the basis of said comparison, predicting the enzymatic degradation profile of said starch in vivo" in claims 22 and 29, renders those claims and their dependents indefinite. It is not clear what process steps are encompassed or excluded, or even required by the claimed "predicting" step. Moreover, it is unclear why one would need a hydrolyzed standard starch sample to predict the *in vivo* degradation profile of the test sample starch, since the

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enzymatic degradation profile of the test sample starch is itself predictive of the *in vivo* digestibility of the test sample. Because it is unclear what steps beyond the "comparison" step are required to predict the enzymatic degradation of a particular starch, the metes and bounds of the claimed subject matter are not clear.

Also, the recitation "said starch" at the end of each of claims 22 and 29 lacks clear antecedent basis in the claims, because the claims previously recite both "native starch" and "standard starch."

Claim 28 is also indefinite because it depends from cancelled claim 2.

Claim 31 is also indefinite because the recitation "any one of" suggests that the claim is intended to be a multiple dependent claim, whereas claim 31 only depends from claim 29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

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art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 18, 20-23, 25, 26, 28-30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring et al (Food Chemistry 28:97-109 (1988)).

Ring discloses the treatment of raw starch granules from pea, maize, wheat and potato with pancreatic α -amylase at 37°C in 0.05 M phosphate buffer at pH 6.9, in 0.04% NaCl (0.0068 M), for 24 hours, wherein the extent of hydrolysis is determined by two methods which colorimetrically assess the amount sugar released from the raw starch. See page 99, fourth full paragraph ("For the physico-chemical studies"); see also page 101, last paragraph; see also Table 3 on page 102. The purpose of the hydrolysis assays in Ring was to assess, or using language of applicant's claims, "predict" the *in vivo* digestibility of the various starches tested. See "Discussion" at pages 105-108, in particular statements such as that on page

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107, stating that "[t]he present study confirms that a variety of poorly digestible starches exist in foods at levels which can be controlled by the food technologist." Thus, the assays performed in Ring include the "predicting" step recited in independent claims 22 and 29.

Ring differs from independent claims 17, 22 and 29 and their dependents, in that, while it is not clear that the enzyme units used by Ring are different than those used in the claims, Ring appears to use lower amounts of α -amylase than the amount recited in the claims. However, the artisan of ordinary skill would have readily determined, through routine experimentation, amounts of enzyme suitable for use in the assays of Ring. Thus, applicant's claimed selection of an enzyme amount which reasonably would have been expected to have functioned suitably in Ring's assays must be considered obvious under § 103(a), absent some demonstration that the claimed enzyme concentration produces an unexpected result. Moreover, inasmuch as it appears that applicant's claims recite the use of more enzyme than Ring, the artisan of ordinary skill would have considered the use of additional enzyme obvious under § 103(a) since the use of more enzyme would have been expected to have increased the speed of the assay. The claims must be therefore be considered obvious in this regard.

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Ring also differs from the claims in that Ring does not explicitly disclose the use of an undigested starch preparation as a control for measuring the color of undigested starch contacted with color-generating reagent, as recited in claims 21 and 33. It would appear that such a control would necessarily have been performed. However, it cannot be truly said that the use of a control is inherent in Ring's process. Despite this, the use of an untreated control or blank in colorimetric enzyme assays is extremely well known in the art. Thus, the claimed use thereof must be considered obvious over the cited reference.

Ring also differs from claims 20, 25, 28 and 32 in the fact that Ring does not disclose the filtering step recited therein. However, in view of the fact that the undigested product, raw starch, is insoluble, the use of a separation step, such as centrifugation or the claimed filtration, to separate the insoluble reactant from the soluble product to be measured must be considered obvious since such a step would have been reasonably expected to ensure the accuracy of the measurement of the amount of product generated by the process.

Ring differs from claims 18, 23, 26 and 30 in the fact that Ring does not disclose the measurement of the color at the claimed wavelength. However, the determination of a suitable wavelength for use in the colorimetric assays disclosed in Ring

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would have been considered a matter of routine optimization on the part of the artisan of ordinary skill, the artisan recognizing that using different wavelengths would have affected the result of the measurement process. The selection of the wavelength recited in claims 18, 23, 26 and 30 must therefore be considered obvious.

Claims 17-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring et al (Food Chemistry 28:97-109 (1988)) in view of Bernfeld (Methods Enzymol. 1:149-159 (1955)).

As discussed above, Ring discloses the treatment of raw starch granules from pea, maize, wheat and potato with pancreatic α -amylase under the claimed process conditions, thereby anticipating and/or rendering obvious claims 1-3 and 8-16. Ring differs from the claims in that Ring does not use 3,5 dinitrosalicylic acid as the color-generating agent for determining the amount of sugar released from the raw starch granules.

However, Bernfeld clearly discloses that 3,5 dinitrosalicylic acid is a suitable reagent for determining the amount of sugars released from starch by α -amylase digestion. See pages 149-150. Moreover, Bernfeld clearly discloses that the assay method using 3,5 dinitrosalicylic acid is advantageous

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in that it is "simple, reliable and rapid." Page 149. As an aside, note Bernfeld's disclosure of the use of a blank for control or comparison purposes. See sentence spanning pages 149-150. Thus, the artisan of ordinary skill, recognizing from Bernfeld the advantages of using the assay method disclosed therein, clearly would have been motivated to have used the 3,5 dinitrosalicylic acid as the colorimetric agent for determining the degree of starch digestion in the methods of Ring. A holding of obviousness is therefore required.

All of applicant's argument regarding the pending grounds of rejection has been fully considered but is not persuasive of error. With respect to the rejections under § 112, second paragraph, even by removing the passive "use" language from the claims, it is unclear what is encompassed by the prediction step in applicant's claims. On the current record it appears that any time the claimed assay is performed, a digestibility prediction will be inherently made. Thus, it is simply not clear what actual steps are required by the prediction step, other than the other steps recited in the claims.

With respect to the issue of obviousness, contrary to applicant's argument, Ring's disclosure is clearly directed to predicting the *in vivo* digestibility of various starches,

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including native or "raw" starches, by performing *in vitro* assays using the enzyme which actually digests the starches *in vivo*, pancreatic α -amylase. The fact that Ring's authors are desirous of preparing a food product with improved nutritional properties does not negate the fact that they are performing *in vitro* digestibility assays in furtherance of that goal. Ring's *in vitro* assays predict *in vivo* starch digestibility, exactly like the claimed assays.

With respect to the argued quantitative assays of Ring versus the qualitative properties argued as being identified by the claimed assays, it is unclear how any information can be obtained according to the claimed assays which is not obtained by Ring's assays, since Ring's assays are essentially identical to those claimed, except for the use of less enzyme. With respect to the claimed chloride level, applicant's claims recite the use of "about" 0.01 M chloride ions, and Ring's assay's employ 0.0068 M chloride ions. The value 0.0068 in Ring can be considered to be "about" 0.01, the difference being only 0.0032. Moreover, even if 0.0068 is not considered to be "about" 0.01, the artisan of ordinary skill would have reasonably expected the claimed amount of chloride to have been suitable in Ring's process, in view of the small difference between the amount recited in the claims, and the amount described by Ring. Thus,

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absent some demonstration of an unexpected result coming from this small change in Ring's process, the rejection must be maintained.

Lastly, with respect to Bernfeld's lack of disclosure of the predictive nature of amylase assays with respect to *in vivo* starch digestibility, applicant is reminded that the Bernfeld is not held as being anticipatory of the claims. Rather, Bernfeld is cited for the fact that the claimed indicator was known at the time of applicant's invention to be useful as an indicator of the degree of starch degradation in an amylase assay. Thus, one of ordinary skill clearly would have recognized that Bernfeld's indicator would have been useful in Ring's amylase assays. Moreover, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

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ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

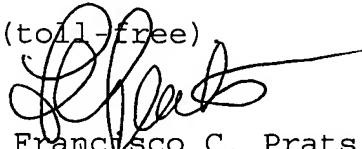
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the

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organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)



Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP